

101.541-06 – including *Taq* pol., IFU-01
101.541-06u – without *Taq* pol., IFU-02

Visit <https://labproducts.caredx.com> for
“Instructions for Use” (IFU)

Lot No.: **7F5**

Lot-specific information
Olerup SSP[®] HLA-B*37

Product number:	101.541-06 – including <i>Taq</i> polymerase 101.541-06u – without <i>Taq</i> polymerase
Lot number:	7F5
Expiry date:	2021-10-01
Number of tests:	6
Number of wells per test:	29+1
Storage - pre-aliquoted primers:	dark at -20°C
- PCR Master Mix:	-20°C
- Adhesive PCR seals	RT
- Product Insert	RT

This Product Description is only valid for Lot No. 7F5.

Complete product documentation consists of generic Instructions for Use (IFU), lot specific Product Insert, Worksheet and Certificate.

**CHANGES COMPARED TO THE PREVIOUS OLERUP SSP[®]
HLA-B*37 LOT (4D3).**

The HLA-B*37 kit is updated for new alleles to enable separation of:

- Confirmed¹ alleles as listed in the IMGT/HLA database
- Polymorphisms in exons outside of the region encoding the peptide binding domain
- Null and Alternatively expressed alleles

The format of the Product Insert and Worksheet have been changed.

Four wells have been added to HLA-B*37, wells **27 to 30**.

¹As described in section Uniquely Identified Alleles.

The HLA-B*37 primer set, specificity and interpretation tables have been updated for the HLA-B alleles described since the previous *Olerup SSP[®] HLA-B*37* lot was made (**Lot No. 4D3**). The kit design is based on IMGT/HLA database 3.29.0.

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The primers of the wells detailed below has been exchanged, added or modified.

Well	5'-primer	3'-primer	rationale
13	Moved	Moved	Primer pairs moved to wells 28 and 29 for improved HLA-specific amplification.
26	Added	Added	Negative control moved to well 29, primer pair added for the B*37:58 allele.
27	New	New	New primer pair added for the B*37:68 allele.
28	Added	Added	Primer pair added from well 13 for improved HLA-specific amplification.
29	Added	Added	Primer pair added from well 13 for improved HLA-specific amplification.
30	-	-	Negative control added from well 26.

Changes in revision R01 compared to R00:

1. The expiration date has been altered due to extension of shelf-life.

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Well **30** contains Negative Control primer pairs, that will amplify more than 95% of the *Olerup* SSP[®] HLA Class I, DRB, DQB1, DPB1 and DQA1 amplicons as well as all the amplicons generated by the control primer pairs matching the human growth hormone gene.

HLA-specific PCR product sizes range from 75 to 200 base pairs.
The PCR product generated by the positive control primer pair is 430 base pairs.

Length of PCR product	105	200	105	80	75	80	85
5'-primer¹	164	340	440	45	45	43	36
	5'-CAC ^{3'}	5'-Agg ^{3'}	5'-TTA ^{3'}	5'-Tgg ^{3'}	5'-Tgg ^{3'}	5'-Tgg ^{3'}	5'-TAC ^{3'}
							36
							5'-TAT ^{3'}
3'-primer²	231	2nd I	507	59	58	57	47
	5'-TgC ^{3'}	5'-AAA ^{3'}	5'-TTg ^{3'}	5'-CTC ^{3'}	5'-ggC ^{3'}	5'-CTC ^{3'}	5'-ACA ^{3'}
							48
							5'-gCA ^{3'}
							48
							5'-gCC ^{3'}
							52
							5'-TgT ^{3'}
A*	+	+	+				
B*	+	+	+				
C*	+	+	+				
DRB1				+	+		
DRB3				+	+		
DRB5				+			
DQB1					+		
DPB1						+	
DQA1							+

¹The nucleotide position for HLA class I genes and the codon for HLA class II genes, in the 2nd or 3rd exon, matching the specificity-determining 3'-end of the primer is given. Nucleotide and codon numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

²The nucleotide position for HLA class I genes and the codon for HLA class II genes, in the 2nd or 3rd exon or the 2nd intron, matching the specificity-determining 3'-end of the primer is given in the anti-sense direction. Nucleotide and codon numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

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PRODUCT DESCRIPTION

HLA-B*37 SSP typing

CONTENT

The primer set contains 5'- and 3'-primers for identifying the B*37:01 to B*37:68 alleles.

PLATE LAYOUT

Each HLA-B*37 test consists of 30 PCR reactions in a 32 well cut PCR plate. Wells 31 and 32 are empty.

1	2	3	4	5	6	7	8
9	10	11	12	13	14	15	16
17	18	19	20	21	22	23	24
25	26	27	28	29	NC	empty	empty

The 32 well PCR plate is marked with ‘HLA-B*37’ in silver/gray ink.

Well No. 1 is marked with the Lot No. ‘7F5’.

Wells 1 to 29 – HLA-B*37 high resolution primers.

Well 30 – Negative Control (NC).

A faint row of numbers is seen between wells 1 and 2 or wells 7 and 8 of the PCR trays. These stem from the manufacture of the trays, and should be disregarded.

The PCR plates are heat-sealed with a PCR-compatible foil.

Please note: When removing each 32 well PCR plate, make sure that the remaining plates stay sealed. Use a scalpel or a similar instrument to carefully cut the foil between the plates.

INTERPRETATION

Due to the sharing of sequence motifs between HLA-B alleles, non-HLA-B*37 alleles will be amplified by some primer mixes. For further details see Specificity Table.

UNIQUELY IDENTIFIED ALLELES

All the HLA-B*37, i.e. **B*37:01 to B*37:68**, recognized by the HLA Nomenclature Committee in August 2017^{1,2} will be amplified by the primers in the HLA-B*37 SSP kit.

The HLA-B*37 kit enables separation of the confirmed HLA-B*37 alleles as listed in the IMGT/HLA database. An HLA allele is listed as confirmed by IMGT/HLA if it has been sequenced by more than a single laboratory or from multiple sources. Current allele confirmation status for HLA-B*37 alleles is listed below.

The following HLA-B*37 alleles can be distinguished by the different sizes of the HLA-specific PCR product:

Alleles	Primer mix
B*37:24, 37:27	21
B*37:26, 37:46	10

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¹HLA-B alleles listed on the IMGT/HLA web page 2017-August-10, release 3.29.0, www.ebi.ac.uk/imgt/hla.

²Alleles that have been deleted from or renamed in the official WHO HLA Nomenclature up to and including the last IMGT/HLA database release can be retrieved from web page <http://hla.alleles.org/alleles/deleted.html>.

ALLELE CONFIRMATION STATUS

Allele	Status ¹	Allele	Status ¹	Allele	Status ¹
B*37:01:01	Confirmed	B*37:19:01	Unconfirmed	B*37:48	Confirmed
B*37:01:02	Confirmed	B*37:19:02	Unconfirmed	B*37:49	Unconfirmed
B*37:01:03	Confirmed	B*37:20	Unconfirmed	B*37:50	Unconfirmed
B*37:01:04	Unconfirmed	B*37:21	Confirmed	B*37:51	Unconfirmed
B*37:01:05	Unconfirmed	B*37:22	Confirmed	B*37:52	Confirmed
B*37:01:06	Unconfirmed	B*37:23	Unconfirmed	B*37:53	Unconfirmed
B*37:01:07	Confirmed	B*37:24	Unconfirmed	B*37:54	Unconfirmed
B*37:01:08	Unconfirmed	B*37:25	Unconfirmed	B*37:55	Unconfirmed
B*37:01:09	Confirmed	B*37:26	Unconfirmed	B*37:56	Unconfirmed
B*37:01:10	Unconfirmed	B*37:27	Unconfirmed	B*37:57	Unconfirmed
B*37:01:11	Unconfirmed	B*37:28	Unconfirmed	B*37:58	Confirmed
B*37:02	Unconfirmed	B*37:29	Unconfirmed	B*37:59	Unconfirmed
B*37:03N	Confirmed	B*37:30N	Unconfirmed	B*37:60	Unconfirmed
B*37:04:01	Confirmed	B*37:31	Unconfirmed	B*37:61	Unconfirmed
B*37:04:02	Confirmed	B*37:32	Unconfirmed	B*37:62	Unconfirmed
B*37:05	Unconfirmed	B*37:33N	Unconfirmed	B*37:63	Unconfirmed
B*37:06:01	Confirmed	B*37:34	Unconfirmed	B*37:64	Unconfirmed
B*37:06:02	Unconfirmed	B*37:35	Confirmed	B*37:65	Unconfirmed
B*37:07	Confirmed	B*37:36	Unconfirmed	B*37:66	Unconfirmed
B*37:08	Unconfirmed	B*37:37	Unconfirmed	B*37:67	Unconfirmed
B*37:09	Unconfirmed	B*37:38	Unconfirmed	B*37:68	Unconfirmed
B*37:10	Confirmed	B*37:39	Unconfirmed		
B*37:11	Unconfirmed	B*37:40	Unconfirmed		
B*37:12	Unconfirmed	B*37:41	Unconfirmed		
B*37:13	Unconfirmed	B*37:42N	Confirmed		
B*37:14	Unconfirmed	B*37:43	Unconfirmed		
B*37:15	Unconfirmed	B*37:44	Unconfirmed		
B*37:16Q	Unconfirmed	B*37:45	Unconfirmed		
B*37:17	Confirmed	B*37:46	Unconfirmed		
B*37:18	Confirmed	B*37:47	Unconfirmed		

¹Allele status “confirmed” or “unconfirmed” as listed on the IMGT/HLA web page 2017-August-10, release 3.29.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

Results file with resolution in HLA-B*37 homo- and heterozygotes is available upon request.

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Lot-specific information
SPECIFICITY TABLE

HLA-B*37 SSP subtyping

Specificities and sizes of the PCR products of the 29+1 primer mixes used for
HLA-B*37 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-B*37 alleles ³	Other amplified HLA-B alleles
1	210 bp	800 bp	*37:01:01-37:01:11, 37:03N-37:06:02, 37:08, 37:10-37:11, 37:13-37:18, 37:20-37:38, 37:41-37:43, 37:45-37:55, 37:57-37:65, 37:67-37:68	*08:49, C*07:68, C*07:302
2⁴	95 bp 135 bp	800 bp	*37:02 *37:28	*07:197, 15:342, 27:01-27:05:15, 27:05:17-27:05:32, 27:08, 27:10, 27:12-27:13, 27:15-27:18, 27:23, 27:25-27:26, 27:28-27:29, 27:31, 27:36-27:40, 27:42, 27:44-27:45, 27:47-27:69, 27:71-27:75, 27:77, 27:79-27:80, 27:82-27:90:04, 27:92-27:101, 27:103-27:105, 27:108-27:124, 27:126, 27:128-27:129, 27:131-27:135, 27:137, 27:139-27:149, 27:151-27:152, 27:155-27:163, 47:04-47:05, 48:26, A*32:89 *07:27, 07:236, 08:126, 08:131, 08:139, 27:03, 27:05:02:01-27:05:20, 27:05:22-27:05:32, 27:07:01-27:07:06, 27:09-27:10, 27:13-27:14, 27:16-27:17, 27:19, 27:27-27:29, 27:32, 27:34-27:35, 27:37-27:39, 27:41, 27:43, 27:45-27:48, 27:50:01-27:51, 27:54-27:56, 27:58-27:60, 27:64N, 27:70-27:74, 27:76, 27:78, 27:80-27:82, 27:84-27:85, 27:87-27:88, 27:90:01-27:90:04, 27:92-27:94N, 27:96:01-27:99, 27:101, 27:104, 27:111, 27:116-27:118, 27:121-27:124, 27:127-27:130, 27:132-27:133, 27:135-27:137, 27:139-27:141, 27:143-27:146, 27:148, 27:150-27:152, 27:155, 27:159-27:162, 27:164, 38:17
3	200 bp 235 bp	1070 bp	*37:13 *37:03N	
4	200 bp 240 bp	1070 bp	*37:13 *37:04:01-37:04:02, 37:39, 37:48	*15:32:01-15:32:02, 15:299, 18:18, 35:48, 44:209, 53:07, C*03:90, C*03:103, C*03:178, C*03:300, C*07:03, C*07:186, C*07:242, C*07:265, C*07:516
5	210 bp	1070 bp	*37:01:01-37:04:02, 37:06:01-37:09, 37:12-37:13, 37:15-37:21, 37:23-37:33N, 37:35-37:36, 37:38-37:66, 37:68	*07:27, 07:236, 07:273, 08:126, 18:54, 38:17

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6	145 bp	1070 bp	*37:05, 37:11, 37:14 ^w , 37:37, 37:67	*07:65, 07:133-07:134, 08:32, 08:133, 08:155, 08:180, 15:46, 15:53, 15:106, 15:143, 15:202, 15:212, 15:239, 15:308, 15:376, 18:01:01:01-18:08, 18:10-18:15, 18:17N-18:36, 18:38-18:53, 18:55-18:65, 18:68-18:124, 18:126-18:135, 18:137- 18:139, 35:01:01:01-35:01:38, 35:01:40- 35:08:01:02, 35:08:03-35:08:04, 35:08:06- 35:24:02, 35:27-35:45, 35:47-35:48, 35:50- 35:72, 35:74-35:197, 35:199-35:206, 35:208-35:209, 35:211-35:221, 35:223- 35:247, 35:249-35:253, 35:255-35:270, 35:272-35:292, 35:294-35:310, 35:312- 35:328, 35:330-35:349, 39:19:01-39:19:02, 39:69, 40:01:01-40:11:02, 40:14:01-40:16, 40:18, 40:20, 40:22N-40:40, 40:42-40:45, 40:48-40:75, 40:77-40:92, 40:94-40:95, 40:97-40:108, 40:111-40:116, 40:118N- 40:136, 40:138-40:156, 40:158-40:187, 40:189-40:200, 40:202-40:207, 40:209- 40:264, 40:266-40:291N, 40:293-40:339, 40:341-40:360, 41:01:01-41:04, 41:05 ^w , 41:06-41:25, 41:27-41:45N, 41:47-41:52, 44:09, 44:46, 44:75, 44:90, 44:129, 44:131, 44:254, 45:01:01-45:15, 45:17-45:20, 46:40:01-46:40:02, 47:02, 47:03 ^w , 48:41, 50:01:01:01-50:02, 50:04-50:05, 50:07- 50:20, 50:31-50:53, 56:06, 56:45, 58:64, 78:01:01:01-78:09
7	130 bp	1070 bp	*37:06:01-37:06:02, 37:42N	*40:188, 44:257, 47:01:01:01-47:01:03, 47:05-47:10
	195 bp		*37:36	
8⁴	120 bp	1070 bp	*37:07	*07:02:01:01-07:18:02, 07:20-07:24, 07:26- 07:32, 07:34-07:39, 07:41-07:47, 07:49N- 07:50, 07:52, 07:54-07:59, 07:61-07:99, 07:101-07:121, 07:123-07:138, 07:140- 07:154, 07:156-07:163, 07:166-07:201N, 07:203-07:208, 07:210-07:219, 07:221- 07:222, 07:224-07:225, 07:227-07:234, 07:236-07:260, 07:262-07:296, 08:79, 08:156, 15:138, 15:230, 15:241, 15:297, 40:15-40:16, 40:23, 40:32, 40:98, 40:158, 40:183, 40:198, 40:355, 44:150, 48:05, 48:08, 48:15, C*02:23, C*03:260, C*04:77
9⁴	80 bp	1070 bp	*37:08	*07:27, 07:236, 08:126, 08:131, 08:139, 18:54, 27:92, 38:17, 53:03, A*68:112:02
	125 bp		*37:42N	
	155 bp		*37:30N	
	215 bp		*37:22	
	495 bp			*15:209N
10^{4,5}	110 bp	1070 bp	*37:26	
	145 bp		*37:14	
	310 bp		*37:46	
11⁴	95 bp	1070 bp	*37:18	
	215 bp		*37:09	*07:04, 07:19, 07:25, 07:146,

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				08:01:01:01-08:05, 08:07-08:08N, 08:10-08:11, 08:14-08:15, 08:17-08:19N, 08:21-08:24, 08:26:01-08:39, 08:41-08:48, 08:50-08:54:02, 08:56:01-08:59:02, 08:61-08:69, 08:71-08:78, 08:80-08:83, 08:85-08:88, 08:90-08:106, 08:108-08:128, 08:130-08:142, 08:144-08:155, 08:157-08:170, 08:172-08:180, 08:182-08:183, 35:87, 41:02:01-41:02:07, 41:04, 41:10-41:11, 41:13, 41:15, 41:18-41:19, 41:23-41:24, 41:27, 41:31, 41:36, 41:38-41:43, 41:45N-41:47, 41:49, 41:51-41:52, 42:01:01-42:02:01:02, 42:05:01-42:12, 42:14-42:18, 42:20-42:24, 44:106, 44:158, 44:166, 44:213
12	355 bp 205 bp	1070 bp	*37:43 *37:01:01-37:07, 37:09-37:54, 37:56-37:61, 37:63-37:66, 37:68	*13:23, 13:55, 15:71, 15:175, 15:204, 15:210, 15:212, 15:225, 15:344, 15:381, 18:12:01-18:12:02, 27:01-27:21, 27:24-27:36, 27:38-27:91, 27:93-27:108, 27:110-27:156, 27:158-27:164, 35:63, 35:317, 39:101, 40:01:01-40:06:14, 40:06:16-40:07, 40:09, 40:11:01-40:11:02, 40:13-40:16, 40:18-40:20, 40:22N-40:24, 40:26-40:39, 40:42-40:48, 40:50-40:57, 40:59-40:67, 40:70:01-40:105, 40:107-40:109, 40:111-40:128, 40:130:01-40:136, 40:138-40:163, 40:165, 40:167-40:190, 40:192-40:209, 40:211-40:218, 40:220-40:228, 40:230-40:231, 40:233-40:243, 40:245-40:312, 40:314-40:317, 40:319-40:324, 40:326-40:327, 40:329-40:341, 40:343-40:356, 40:358-40:360, 41:01:01-41:32, 41:34-41:46, 41:48-41:52, 44:15, 44:18, 44:55, 44:103, 44:131, 44:188, 44:212, 45:01:01-45:20, 48:22, 48:30, 49:01:01:01-49:09, 49:11-49:14, 49:16-49:23, 49:27-49:30, 49:32-49:48, 50:01:01:01-50:02, 50:04-50:12, 50:14, 50:16-50:20, 50:31-50:42, 50:44-50:53, 52:51
13	255 bp	800 bp	*37:10	*13:23, 13:55, 18:09, 27:01, 27:142, 40:47, 40:96, 40:157, 40:201, 44:15, 44:55, 44:103, 44:188, 44:212, 49:02
14⁴	110 bp	1070 bp	*37:47	*27:04:01-27:04:06, 27:06, 27:24-27:25, 27:66N, 27:68-27:69, 27:100, 27:103, 27:105, 27:109, 27:112-27:115, 27:138, 27:147, 27:149
	245 bp		*37:11, 37:37, 37:67	*07:143, 08:62, 15:71, 15:175, 15:204, 15:210, 15:212, 15:225, 15:344, 15:381, 15:426, 18:01:01:01-18:01:12, 18:01:14-18:01:20, 18:01:22-18:03, 18:05-18:08, 18:10-18:15, 18:17N-18:24, 18:26-18:42, 18:44:01-18:48, 18:50-18:53, 18:55-18:66, 18:68-18:78, 18:80-18:106, 18:109-18:124, 18:126-18:131, 18:133-18:135, 18:137-18:139, 27:08, 27:12, 27:18, 27:26, 27:33,

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15	135 bp	1070 bp	*37:11, 37:37, 37:67	*07:65, 07:134, 08:32, 08:133, 08:180, 15:202, 15:239, 15:308, 15:376, 18:01:01:01-18:01:20, 18:01:22-18:08, 18:10-18:15, 18:17N-18:36, 18:38-18:47, 18:50-18:53, 18:55-18:65, 18:68-18:78, 18:80-18:106, 18:109-18:124, 18:126-18:131, 18:133-18:135, 18:137-18:139, 35:01:01:01-35:02:02, 35:02:04-35:03:02, 35:03:04-35:08:01:02, 35:08:03-35:08:04, 35:08:06-35:18, 35:20:01-35:24:02, 35:28-35:45, 35:48, 35:50-35:55, 35:57-35:62, 35:64:01-35:72, 35:74-35:153, 35:155-35:197, 35:199-35:202, 35:204-35:206, 35:208-35:209, 35:211-35:216N, 35:218-35:221, 35:223-35:253, 35:255-35:270, 35:272-35:273, 35:275-35:298, 35:300-35:310, 35:312-35:316, 35:318-35:328, 35:330-35:349, 39:19:01-39:19:02, 40:185, 40:209, 40:308, 40:350, 46:40:01-46:40:02, 56:06, 56:45, 58:64, 78:01:01:01-78:05, 78:07-78:08
	315 bp		*37:45	
16	170 bp	1070 bp	*37:09, 37:12, 37:35, 37:56	*07:04, 07:19, 07:25, 07:146, 08:01:01:01-08:01:22, 08:01:24-08:05, 08:07-08:12:03, 08:15-08:19N, 08:21-08:24, 08:26:01-08:27, 08:29-08:39, 08:41-08:48, 08:50-08:54:02, 08:56:01-08:69, 08:71-08:73, 08:75-08:78, 08:80-08:86N, 08:88-08:110, 08:112-08:142, 08:144-08:155, 08:157-08:170, 08:172-08:184, 15:51, 15:83, 15:179:01-15:179:02, 15:199, 15:218Q, 18:56, 18:113, 35:38, 35:87, 35:115,

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101.541-06u – without *Taq* pol., IFU-02

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Lot No.: **7F5**

Lot-specific information

	195 bp		*37:20	35:169, 35:260, 38:30, 40:136, 40:231, 40:279, 41:01:01-41:09, 41:11-41:51, 42:01:01-42:02:01:02, 42:04-42:18, 42:21-42:24, 44:14, 44:17, 44:51, 44:62, 44:123, 44:166, 44:213, 44:230, 45:09, 45:14, 51:08:01-51:08:02, 51:20, 51:36, 51:44N, 51:97, 51:141, 51:153, 52:19, 53:22, 55:20, 55:56, 56:13, 57:09, 57:24, 82:01-82:03
17⁷	165 bp 195 bp	1070 bp	*37:25 *37:20	*45:03
18	135 bp	1070 bp	*37:11, 37:14, 37:29, 37:37, 37:67	*07:65, 07:134, 08:32, 08:133, 08:180, 15:202, 15:239, 15:308, 15:376, 18:01:01:01-18:01:20, 18:01:22-18:08, 18:10-18:15, 18:17N-18:36, 18:38-18:47, 18:50-18:53, 18:55-18:65, 18:68-18:78, 18:80-18:106, 18:109-18:124, 18:126-18:131, 18:133-18:135, 18:137-18:139, 35:01:01:01-35:03:02, 35:03:04-35:08:01:02, 35:08:03-35:08:04, 35:08:06-35:18, 35:20:01-35:24:02, 35:28-35:45, 35:48, 35:50-35:51, 35:53N-35:55, 35:57-35:62, 35:64:01-35:72, 35:74-35:153, 35:155-35:197, 35:199-35:202, 35:204-35:206, 35:208-35:209, 35:211-35:216N, 35:218-35:253, 35:255-35:270, 35:272-35:273, 35:275-35:292, 35:294-35:298, 35:300-35:309, 35:312-35:316, 35:318-35:349, 39:19:01-39:19:02, 40:185, 40:209, 40:308, 40:350, 46:40:01-46:40:02, 56:06, 56:45, 58:64, 78:01:01:01-78:05, 78:07-78:08
19	215 bp	1070 bp	*37:21, 37:67	*08:62, 18:07:01-18:07:02, 18:29, 18:79, 18:136, 27:23, 35:50, 35:84, 35:162, 35:217, 35:231, 35:280, 35:323, 40:07-40:08, 40:13, 40:68, 40:106, 40:162, 40:220, 40:232, 41:46, 51:103, 51:116, 51:151
20	315 bp 195 bp 230 bp	800 bp	*37:45 *37:36 *37:16Q, 37:39, 37:48	*15:32:01-15:32:02, 15:299, 35:48, 44:209, 53:07, C*03:90, C*03:103, C*03:178, C*03:300, C*07:03, C*07:186, C*07:242, C*07:265, C*07:494Q
21⁵	165 bp 195 bp 270 bp	1070 bp	*37:27 *37:33N *37:24	*27:57 *27:94N *27:122, 40:152
22	175 bp	1070 bp	*37:17	*40:153
23^{4,6}	90 bp	1070 bp	*37:19:01	*14:10, 35:59:01, 35:242, 38:20, 39:42, 39:106, 44:117, 44:251, C*15:05:08, C*15:140, C*17:01:10
24	350 bp 170 bp	1070 bp	*37:23, 37:43 *37:52	*15:227, 27:69, 40:213, 51:32, 58:52 *54:02, C*03:278, C*06:77, C*16:86

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Lot No.: **7F5**

Lot-specific information

25	375 bp	1070 bp	*37:02	*15:129, 15:342, 15:395, 27:18, 27:29, 47:04-47:05, 48:21, 48:26
26	220 bp	1070 bp	*37:58	*38:61
27⁴	80 bp	1070 bp	*37:68	
28	170 bp	1070 bp	*37:15	
29	195 bp	1070 bp	*37:33N	*27:94N
30⁸	-	-	Negative Control	

¹Alleles are assigned by the presence of specific PCR product(s). However, the sizes of the specific PCR products may be helpful in the interpretation of HLA-B*37 SSP typings.

When the primers in a primer mix can give rise to HLA-specific PCR products of more than one length this is indicated if the size difference is more than 20 base pairs. Size differences of 20 base pairs or less are not given. For high resolution SSP kits, the alleles listed are specified according to amplicon length.

Nonspecific amplifications, i.e. a ladder or a smear of bands, may sometimes be seen. GC-rich primers have a higher tendency of giving rise to nonspecific amplifications than other primers.

PCR fragments longer than the control bands may sometimes be observed. Such bands should be disregarded and do not influence the interpretation of the SSP typings.

PCR fragments migrating faster than the control bands, but slower than a 400 bp fragment may be seen in some gel read-outs. Such bands can be disregarded and do not influence the interpretation of the SSP typings.

Some primers may give rise to primer oligomer artifacts. Sometimes this phenomenon is an inherent feature of the primer pair(s) of a primer mix. More often it is due to other factors such as too low amount of DNA in the PCR reactions, taking too long time in setting up the PCR reactions, working at elevated room temperature or using thermal cyclers that are not pre-heated.

²The internal positive control primer pairs amplify segments of the human growth hormone gene. The internal positive control bands are 1070 or 800 base pairs respectively, well distribution as outlined in the table. Well number 1 contains the shorter, 800 bp, internal positive control band. The well distribution of the internal controls can help in orientation of the kit on gel photo, as well as allow for kit identification. In the presence of a specific amplification the intensity of the control band often decreases.

³For several HLA Class I alleles 1st and/or 4th exon(s) and beyond, as well as intron nucleotide sequences, are not available. In these instances it is not known whether some of the primers of the SSP sets are completely matched with the target sequences or not. Assumption is made that unknown sequences in these regions are conserved within allelic groups.

⁴HLA-specific PCR products shorter than 125 base pairs have a lower intensity and are less sharp than longer PCR products.

⁵Primer mixes 10 and 21 may have tendencies of unspecific amplifications.

⁶Primer mix 23 has a tendency of giving rise to primer oligomer formation.

⁷Primer mix 17 may give rise to a lower yield of HLA-specific PCR product than the other B*37 primer mixes.

⁸Primer mix 30 contains a negative control, which will amplify more than 95% of HLA amplicons as well as the amplicons generated by control primer pairs. PCR product sizes range from 75 to 200 base pairs. The PCR product generated by the control primer pair is 430 base pairs.

'w', might be weakly amplified.

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Lot No.: **7F5**

Lot-specific information

PRIMER SPECIFICATION

Well No.	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec. PCR product	210	95	200	200	210	145	130	120	80	110	95	205
		135	235	240			195		155	310	355	
									215			
									495			
Length of int. pos. control ¹	800	800	1070	1070	1070	1070	1070	1070	1070	1070	1070	1070
5'-primer(s) ²	368 5'-gTC 3'	206 5'-AgA 3'	142 5'-TCT 3'	368 5'-gTC 3'	142 5'-TCT 3'	206 5'-gAA 3'	149 5'-ggT 3'	527 5'-TgA 3'	126 5'-ggA 3'	206 5'-gAC 3'	363 5'-AgC 3'	97 5'-TCC 3'
		363 5'-AAT 3'	368 5'-gTC 3'			206 5'-gAC 3'	206 5'-gAA 3'		215 5'-Cg 3'	3 rd I 5'-Agg 3'	483 5'-gAA 3'	
							215 5'-Cg 3'		261 5'-AAC 3'		3 rd I 5'-Agg 3'	
									355 5'-CCA 3'			
3'-primer(s) ³	538 5'-gTC 3'	301 5'-gTC 3'	337 5'-CTA 3'	527 5'-CCT 3'	311 5'-ggg 3'	311 5'-ggT 3'	301 5'-gTC 3'	605 5'-gCT 3'	301 5'-gTC 3'	275 5'-TCA 3'	538 5'-gTC 3'	259 5'-CTC 3'
		418 5'-gTC 3'	527 5'-CCT 3'	559 5'-CAg 3'	311 5'-ggg 3'				471 5'-gTT 3'	311 5'-ggT 3'	884 5'-ggT 3'	259 5'-CTC 3'
				583 5'-gTg 3'						839 5'-ATT 3'		
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

Well No.	13	14	15	16	17	18	19	20	21	22	23	24
Length of spec. PCR product	255	110	135	170	165	135	215	195	165	175	90	170
		245	315	195	195		315	230	195		350	
									270			
Length of int. pos. control ¹	800	1070	1070	1070	1070	1070	1070	800	1070	1070	1070	1070
5'-primer(s) ²	97 5'-TCC 3'	97 5'-TCC 3'	206 5'-gAC 3'	385 5'-ggg 3'	385 5'-ggg 3'	206 5'-gAC 3'	97 5'-TCC 3'	149 5'-ggT 3'	97 5'-TCC 3'	520 5'-CgA 3'	369 5'-TAC 3'	97 5'-TCC 3'
		704 5'-Tgg 3'	737 5'-Cgg 3'	409 5'-ggC 3'	416 5'-CCg 3'		737 5'-Cgg 3'	368 5'-gTC 3'			3 rd I 5'-Agg 3'	
3'-primer(s) ³	309 5'-gTg 3'	302 5'-ggC 3'	302 5'-ggC 3'	538 5'-gTC 3'	538 5'-gTC 3'	301 5'-gCT 3'	272 5'-TgA 3'	301 5'-gTC 3'	221 5'-ACC 3'	3 rd I 5'-TAT 3'	419 5'-CgA 3'	226 5'-CAC 3'
		774 5'-ggT 3'	916 5'-gAT 3'				916 5'-gAT 3'	559 5'-CAg 3'	251 5'-CCT 3'		872 5'-TCA 3'	
								563 5'-CgT 3'	326 5'-TgC 3'		884 5'-ggT 3'	
Well No.	13	14	15	16	17	18	19	20	21	22	23	24

Well No.	25	26	27	28	29
Length of spec. PCR product	375	220	80	170	195
Length of int. pos. control ¹	1070	1070	1070	1070	1070
5'-primer(s) ²	272 5'-CTC 3'	142 5'-TCT 3'	1049 5'-C 3'	97 5'-TCC 3'	97 5'-TCC 3'
3'-primer(s) ³	362 5'-TAT 3'	320 5'-AgT 3'	1088 5'-AT 3'	227 5'-CTg 3'	251 5'-CCT 3'
Well No.	25	26	27	28	29

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101.541-06u – without *Taq* pol., IFU-02

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Lot No.: **7F5**

Lot-specific information

¹The internal positive control primer pairs amplify segments of the human growth hormone gene. The internal positive control bands are 1070 or 800 base pairs respectively, well distribution as outlined in the table. Well number 1 contains the shorter, 800 bp, internal positive control band. The well distribution of the internal controls can help in orientation of the kit on gel photo, as well as allow for kit identification. In the presence of a specific amplification the intensity of the control band often decreases.

²The nucleotide position matching the specificity-determining 3'-end of the primer is given. Nucleotide numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

³The nucleotide position matching the specificity-determining 3'-end of the primer is given in the anti-sense direction. Nucleotide numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

101.541-06 – including *Taq* pol., IFU-01
 101.541-06u – without *Taq* pol., IFU-02

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Lot No.: **7F5**

Lot-specific information

CELL LINE VALIDATION SHEET																				
HLA-B*37 SSP primer set ²																				
				Well																
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
				Prod. No.:	201318301	201318302	201318303	201437004	201318305	201318306	201437007	201318308	201437009	201437010	201437011	201318312	201786113	201437014	201437015	201437016
	IHWC cell line ¹		B*																	
1	9001 SA		*07:02	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
2	9280 LK707		*52:01	*73:01	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-
3	9011 E4181324		*52:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4	9275 GU373		*15:10	*53:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5	9009 KAS011		*37:01		+	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-
6	9353 SM		*39:01	*51:01	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-
7	9020 QBL		*18:01		-	-	-	-	-	+	-	-	-	-	-	-	-	+	+	-
8	9025 DEU		*35:01		-	-	-	-	-	+	-	-	-	-	-	-	-	-	+	-
9	9026 YAR		*38:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	9107 LKT3		*54:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
11	9051 PITOUT		*44:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	9052 DBB		*57:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	9004 JESTHOM		*27:05		-	+	-	-	-	-	-	-	-	-	+	-	-	-	-	-
14	9071 OLGA		*15:01	*15:20	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
15	9075 DKB		*40:01		-	-	-	-	-	+	-	-	-	-	+	-	+	-	-	-
16	9037 SWEIG007		*40:02		-	-	-	-	-	+	-	-	-	-	+	-	+	-	-	-
17	9282 CTM3953540		*08:01	*55:01	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	+
18	9257 32367		*14:01	*56:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
19	9038 BM16		*18:01		-	-	-	-	-	+	-	-	-	-	-	-	+	+	-	-
20	9059 SLE005		*40:01		-	-	-	-	-	+	-	-	-	-	+	-	+	-	-	-
21	9064 AMALA		*15:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
22	9056 KOSE		*35:03		-	-	-	-	-	+	-	-	-	-	-	-	-	+	-	-
23	9124 IHL		*40:02	*56:02	-	-	-	-	-	+	-	-	-	-	+	-	+	-	-	-
24	9035 JBUSH		*38:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
25	9049 IBW9		*14:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
26	9285 WT49		*58:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
27	9191 CH1007		*07:05	*51:01	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
28	9320 BEL5GB		*44:02	*44:03	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
29	9050 MOU		*44:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
30	9021 RSH		*42:01		-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	+
31	9019 DUCAF		*18:01		-	-	-	-	-	+	-	-	-	-	-	-	+	+	-	-
32	9297 HAG		*41:02		-	-	-	-	-	+	-	-	-	+	+	-	+	-	+	-
33	9098 MT14B		*40:01		-	-	-	-	-	+	-	-	-	-	+	-	+	-	-	-
34	9104 DHIF		*38:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
35	9302 SSTO		*44:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
36	9024 KT17		*15:01	*35:01	-	-	-	-	-	+	-	-	-	-	-	-	-	-	+	-
37	9065 HHKB		*07:02		-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
38	9099 LZL		*15:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
39	9315 CML		*08:01	*27:05	-	+	-	-	-	-	-	-	-	+	+	-	-	-	-	+
40	9134 WHONP199		*13:02	*46:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
41	9055 H0301		*14:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
42	9066 TAB089		*46:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
43	9076 T7526		*46:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
44	9057 TEM		*38:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
45	9239 SHJO		*42:01	*50:01	-	-	-	-	-	+	-	-	-	+	+	-	+	-	+	-
46	9013 SCHU		*07:02		-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
47	9045 TUBO		*51:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
48	9303 TER-ND		*35:01	*44:03	-	-	-	-	-	+	-	-	-	-	-	-	-	-	+	-

101.541-06 – including *Taq* pol., IFU-01
101.541-06u – without *Taq* pol., IFU-02

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Lot No.: **7F5**

Lot-specific information

CELL LINE VALIDATION SHEET																			
HLA-B*37 SSP primer set ²																			
				Well															
				17	18	19	20	21	22	23	24	25	26	27	28	29			
				Prod. No.:	201437017	201318324	201437019	201437020	201562021	201318322	201437023	201562024	201562025	201786126	201786127	201786128	201786129		
IHCW cell line ¹		B*																	
1	9001 SA	*07:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-		
2	9280 LK707	*52:01	*73:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
3	9011 E4181324	*52:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-		
4	9275 GU373	*15:10	*53:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
5	9009 KAS011	*37:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-		
6	9353 SM	*39:01	*51:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
7	9020 QBL	*18:01		-	+	-	-	-	-	-	-	-	-	-	-	-	-		
8	9025 DEU	*35:01		-	+	-	-	-	-	-	-	-	-	-	-	-	-		
9	9026 YAR	*38:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-		
10	9107 LKT3	*54:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-		
11	9051 PITOUT	*44:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-		
12	9052 DBB	*57:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-		
13	9004 JESTHOM	*27:05		-	-	-	-	-	-	-	-	-	-	-	-	-	-		
14	9071 OLGA	*15:01	*15:20	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
15	9075 DKB	*40:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-		
16	9037 SWEIG007	*40:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-		
17	9282 CTM3953540	*08:01	*55:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
18	9257 32367	*14:01	*56:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
19	9038 BM16	*18:01		-	+	-	-	-	-	-	-	-	-	-	-	-	-		
20	9059 SLE005	*40:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-		
21	9064 AMALA	*15:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-		
22	9056 KOSE	*35:03		-	+	-	-	-	-	-	-	-	-	-	-	-	-		
23	9124 IHL	*40:02	*56:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
24	9035 JBUSH	*38:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-		
25	9049 IBW9	*14:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-		
26	9285 WT49	*58:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-		
27	9191 CH1007	*07:05	*51:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
28	9320 BEL5GB	*44:02	*44:03	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
29	9050 MOU	*44:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-		
30	9021 RSH	*42:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-		
31	9019 DUCAF	*18:01		-	+	-	-	-	-	-	-	-	-	-	-	-	-		
32	9297 HAG	*41:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-		
33	9098 MT14B	*40:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-		
34	9104 DHIF	*38:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-		
35	9302 SSTO	*44:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-		
36	9024 KT17	*15:01	*35:01	-	+	-	-	-	-	-	-	-	-	-	-	-	-		
37	9065 HHKB	*07:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-		
38	9099 LZL	*15:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-		
39	9315 CML	*08:01	*27:05	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
40	9134 WHONP199	*13:02	*46:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
41	9055 H0301	*14:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-		
42	9066 TAB089	*46:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-		
43	9076 T7526	*46:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-		
44	9057 TEM	*38:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-		
45	9239 SHJO	*42:01	*50:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
46	9013 SCHU	*07:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-		
47	9045 TUBO	*51:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-		
48	9303 TER-ND	*35:01	*44:03	-	+	-	-	-	-	-	-	-	-	-	-	-	-		

101.541-06 – including *Taq* pol., IFU-01
101.541-06u – without *Taq* pol., IFU-02

Visit <https://labproducts.caredx.com> for
“Instructions for Use” (IFU)

Lot No.: **7F5**

Lot-specific information

¹The provided cell line HLA specificities are retrieved from the <http://www.ihwg.org/hla> web site. The specificity of an individual cell line may thus be subject to change.

²The specificity of each primer solution in the kit has been tested against 48 well characterized cell line DNAs and where applicable, additional cell line DNAs.

No DNAs carrying the allele to be amplified by primer solutions 3, 4, 9, 10, 17, 20 to 24 and 26 to 29 were available. The specificities of the primers in primer solutions 4, 9, 10, 20, 23 and 24 were tested by separately adding one or two additional 3'-primers, respectively one or two additional 5'-primers.

The specificity of the primers in primer solutions 4, 9, 10, 20, 23 and 24 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 3, 21 and 26 to 29 it was only possible to test the 5'-primers, the 3'-primers were not possible to test. In primer solutions 17 and 22 it was only possible to test the 3'-primer, the 5'-primers were not possible to test. In primer solutions 4, 9 to 11, 20 and 23 one or two of the 3'-primers were not possible to test, and in primer 7, 9, 11, 15, 16, 19 and 20 one or two of the 5'-primers were not possible to test. Additional primers in primer solutions 7, 11, 15 and 19 were tested by separately adding one 5'-primer.

101.541-06 – including *Taq* pol., IFU-01
101.541-06u – without *Taq* pol., IFU-02

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Lot No.: **7F5**

Lot-specific information

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